

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ENDO PHARMACEUTICALS INC., :
Plaintiff, : 12 Civ. 8985 (TPG)
- against - :
ACTAVIS INC. and ACTAVIS SOUTH :
ATLANTIC LLC, :
Defendants. :
-----X
ENDO PHARMACEUTICALS INC., :
Plaintiff, : 13 Civ. 3288 (TPG)
- against - :
ROXANE LABORATORIES, INC., :
Defendant. :
-----X
ENDO PHARMACEUTICALS INC. and :
GRÜNENTHAL GMBH, :
Plaintiffs, : 12 Civ. 8060 (TPG)
- against - :
TEVA PHARMACEUTICALS USA, INC., :
and BARR LABORATORIES, INC., :
Defendants. :
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**(captions continued on
next page)**

	-x	
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	:	
Plaintiffs,	:	12 Civ. 8317 (TPG)
- against -	:	
IMPAX LABORATORIES, INC. and THORX LABORATORIES, INC.,	:	
Defendants.	:	
	-x	
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	:	
Plaintiffs,	:	12 Civ. 8318 (TPG)
- against -	:	
SANDOZ INC.,	:	
Defendant.	:	
	-x	
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	:	
Plaintiffs,	:	12 Civ. 8115 (TPG)
- against -	:	
AMNEAL PHARMACEUTICALS, LLC et al.,	:	(captions continued on next page)
Defendants.	:	
	-x	

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ENDO PHARMACEUTICALS INC. and :
GRÜNENTHAL GMBH, :
Plaintiffs, : 12 Civ. 9261 (TPG)

- against - :
PAR PHARMACEUTICAL COMPANIES, :
INC. and PAR PHARMACEUTICAL, INC., :
Defendants. :

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ENDO PHARMACEUTICALS INC., :
Plaintiff, : 13 Civ. 3284 (TPG)

- against - :
PAR PHARMACEUTICAL COMPANIES, :
INC. and PAR PHARMACEUTICAL, INC., :
Defendants. :

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ENDO PHARMACEUTICALS INC., :
Plaintiff, : 13 Civ. 4343 (TPG)

- against - :
RANBAXY LABORATORIES LTD., :
RANBAXY INC., and RANBAXY :
PHARMACEUTICALS INC., :
Defendants. :

(captions continued on
next page)

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ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	:
Plaintiffs,	: 13 Civ. 0435 (TPG)
- against -	:
IMPAX LABORATORIES, INC.,	:
Defendant.	: :
	-----x
ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,	:
Plaintiffs,	: 13 Civ. 0436 (TPG)
- against -	:
ACTAVIS INC. et al.,	:
Defendants.	: :
	-----x

OPINION

These cases concern plaintiff Endo Pharmaceuticals Inc.’s (“Endo”) allegations that defendants infringed its patents on OPANA® ER, an opioid painkiller. In order to protect confidential information exchanged by the parties during the course of this litigation, the parties signed protective orders. These orders restrict the type of work Endo’s litigation counsel—Dechert LLP—may engage in before the U.S. Patent and Trademark Office (“PTO”).

Specifically, the orders prohibit Dechert from engaging in what is known as “patent prosecution” or “claim amendment” before the PTO.

Recently, defendants Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, “Amneal”) filed an action before the PTO that involves many of the same issues. Endo retained Mayer Brown LLP to serve as its primary counsel in that action. Endo now asks the court to rule that the protective orders do not bar the Dechert attorneys who represent Endo before this court from collaborating with attorneys from Mayer Brown about claims and defenses that are at issue in both proceedings.

For the following reasons, Dechert may participate in the PTO proceeding, subject to two restrictions: (1) Dechert may not amend, draft, or consult with Endo or Mayer Brown regarding the amendment of its patent claims and (2) Dechert may not share with Mayer Brown any information designated confidential under any of the protective orders in the related cases or any information about defendants’ Abbreviated New Drug Application (“ANDA”) products.

Statement of Facts

In 2012, Endo brought a patent-infringement action against Amneal for attempting to market a generic pharmaceutical product that allegedly infringes Endo’s OPANA® ER patents. Between 2012 and 2013, Endo filed similar actions against Actavis, Inc., Actavis South Atlantic LLC, and Watson

Pharmaceuticals, Inc.; Roxane Laboratories, Inc.; Teva Pharmaceuticals USA, Inc. and Barr Laboratories, Inc.; Impax Laboratories, Inc. and Thorx Laboratories, Inc.; Sandoz, Inc.; Par Pharmaceutical Companies, Inc. and Par Pharmaceuticals, Inc.; and Ranbaxy Laboratories Ltd., Ranbaxy Inc., and Ranbaxy Pharmaceuticals, Inc. (collectively, the “related defendants”). Endo retained Dechert LLP to serve as its litigation counsel in all of these actions.

In connection with those actions, Endo entered into a series of protective orders. Given that Endo’s litigation with Amneal involves many of the same patents and issues as Endo’s litigation against the related defendants, Amneal’s protective order and the protective orders entered into in the related cases are relevant to the court’s analysis.

Amneal’s protective order states that Dechert may not become “involved in prosecution of patent applications” and limits the use of confidential information learned during the litigation. See Amneal Protective Order, No. 12-cv-8115 (Doc. No. 47). Endo and Impax, a related defendant, entered into a more comprehensive protective order. Impax’s protective order bars Dechert from becoming “involved in prosecution of patent applications . . . or in any drafting or amendment of claims or claim language in any patent office proceeding relating to oxymorphone . . .” (Related Defs. Br., Ex. A at 9).

Since that time, defendant Amneal filed a petition for *inter partes* review before the PTO’s Patent Trial and Appeal Board. Congress created *inter partes*

review in order to provide a “trial proceeding . . . to review the patentability of one or more claims in a patent only on a ground that could be raised under [35 U.S.C.] §§ 102 or 103, and only on the basis of prior art consisting of patents or printed publications.” See USPTO.gov, http://www.uspto.gov/aia_implementation/bpai.jsp (last visited Jul. 29, 2014). The *inter partes* review petition related to these cases asks the PTO to rule on the validity of three of the patents at issue in these actions: U.S. Patent No. 8,309,122, U.S. Patent No. 8,329,216, and U.S. Patent No. 7,851,482.

As mentioned above, Endo hired Mayer Brown LLP to serve as its primary counsel before the PTO. Endo now asks the court to state for the record that Dechert—the law firm representing Endo before this court—may participate in the *inter partes* review proceedings subject to certain limitations.

Amneal and the related defendants oppose that request. Defendants are concerned that if Dechert is permitted to participate in the *inter partes* review proceedings, Endo could amend its claims against defendants based on confidential information Dechert learned during the course of this litigation. As a result, Amneal argues that (1) the protective orders set forth a patent prosecution bar that applies to the PTO proceedings and (2) the court should not grant Dechert an exemption from that prosecution bar. The related defendants argue that Dechert should not be permitted to participate “so long as Endo has the right to amend or draft claims.” (Rel. Defs. Br. at 2).

Significantly, Dechert has made a series of representations to the court and to defendants regarding how it will ensure the protective orders are not violated. In addition to upholding the provisions of the protective orders that govern the use of confidential information, Dechert has stated that it will not “consult with or advise Endo or [Mayer Brown] regarding any amendment or proposed amendments to any claims of the patents-in-suit.” (Endo Br. at 8).

Discussion

A. The Protective Orders Do Not Bar Dechert’s Proposed Participation in the *Inter Partes* Review Proceedings

1. Amneal’s Protective Order

Amneal’s protective order, which states that Dechert may not become “involved in prosecution of patent applications,” does not bar Dechert from participating in the *inter partes* review proceedings. As the PTO’s Patent Trial and Appeal Board recently held in Google Inc. v. Jongerius Panoramic Techs., LLC, an *inter partes* review proceeding is “neither a patent examination nor a patent reexamination. Rather, it is a trial, adjudicatory in nature and constitutes litigation.” Case IPR2013-00191, Paper No. 50, at 4. (P.T.A.B. Feb. 13, 2014). Amneal’s attempts to distinguish Google are unpersuasive.

2. The Related Defendants’ Protective Orders

The related defendants’ protective orders—including Impax’s order which bars Dechert from becoming “involved in prosecution of patent applications . . . or in any drafting or amendment of claims or claim language

in any patent office proceeding relating to oxymorphone. . .”—do not bar Dechert from participating in the *inter partes* review proceedings as long as Dechert is not involved in claim amendment. Dechert and Endo have assured the court and defendants that Dechert will not participate in claim amendment proceedings or discussions with either Endo or Mayer Brown. Thus, in light of these, the related defendants’ protective orders pose no issue here.

However, even if the protective orders did bar Dechert from participating in the *inter partes* review proceedings, the court would make an exception based on the facts of these cases.

B. The Deutsche Bank Factors Favor an Exemption to the Prosecution Bar

In re Deutsche Bank Trust Co. Americas, the Federal Circuit set forth factors that the district court must consider when evaluating a party’s request for an exemption from a patent prosecution bar:

. . . the party seeking an exemption from a patent prosecution bar must show on a counsel-by-counsel basis: (1) that counsel’s representation of the client in matters before the PTO does not and is not likely to implicate competitive decisionmaking related to the subject matter of the litigation so as to give rise to a risk of inadvertent use of confidential information learned in litigation. . . and (2) that the potential injury to the moving party. . . outweighs the potential injury to the opposing party. . . .

605 F.3d 1373, 1381 (Fed. Cir. 2010).

Here, Dechert’s participation is limited to the issues before this court—questions of obviousness and prior art. Those issues need not implicate competitive decisionmaking or claim amendment.

Additionally, Dechert’s coordination with Mayer Brown in defending against the invalidity challenges presents minimal risk of the inadvertent disclosure of confidential information. Although Amneal expresses concern that Dechert might “implicitly transmit to Mayer Brown” recommendations regarding claim amendment or inadvertently disclose Amneal’s confidential information, there is no factual basis for believing Dechert would commit these violations. Furthermore, Amneal’s primary concern is that Dechert will amend claims. This opinion explicitly prohibits Dechert from participating in claim amendment or any discussions related to it. Thus the potential injury to Amneal is minimal.

In contrast, the potential injury to Endo, if Dechert is barred from participating, is high. Endo would be at a significant disadvantage if Dechert is not permitted to assist in the defense of Endo’s patents against the same prior art raised in this litigation. Defendants concede that the prior art references raised by Amneal in its *inter partes* review filings are the same ones presented in this litigation. Dechert has developed extensive knowledge and expertise regarding those challenges. Although Mayer Brown has represented Endo in patent prosecution before the PTO, Mayer Brown does not have experience

representing Endo in the patent litigation involving OPANA® ER. (Endo Br. at 8).

Of interest are the concerns expressed by other district courts about a policy that would “encourage defendants to file for reexamination while excluding plaintiff’s counsel from participating in the reexamination, thereby forcing a plaintiff to defend a patent in two separate venues with two teams of attorneys.” Mirror Worlds, LLC v. Apple, Inc., No. 08-cv-88, 2009 WL 2461808, at *2 (E.D. Tex. Aug. 11, 2009). Forcing Mayer Brown to prepare from scratch the defense that Dechert has already prepared would be a waste of time and resources.

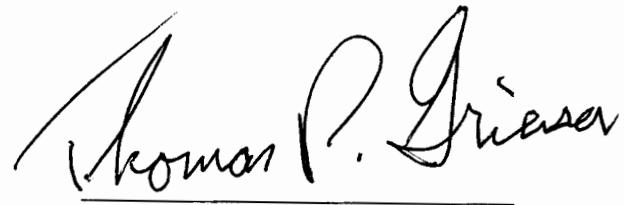
Additionally, the PTO’s decision and choices made before it may have direct consequences in the district court. Xerox Corp. v. Google, Inc., 270 F.R.D. 182, 185 (D. Del. 2010). Thus, Endo has a “legitimate interest in formulating a coherent and consistent litigation strategy.” Id.

Conclusion

Dechert may participate in the *inter parties* review proceedings instituted by Amneal subject to two restrictions. First, Dechert may not amend, draft, or consult with Endo or Mayer Brown regarding the amendment of patent claims. Second, Dechert may not share with Mayer Brown any information designated confidential under the Amneal protective order or any related protective order or share any information about defendants’ ANDA products.

Dated: New York, New York

August 13, 2014



A handwritten signature in black ink, appearing to read "Thomas P. Griesa", is written over a horizontal line.

Thomas P. Griesa

U.S. District Judge

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DATE FILED: <u>8/13/2014</u>	